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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,294	VOORHEES ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23,32-48,50,51,53-58,62-70,73,84-86 and 95-99* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,14,15,21-23,37-39,46-48,50,84 and 85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 8-13,16-20,33,35,36,40-45,51,53-58,62-70,73,86 and 95-99.

DETAILED ACTION

1. Claims 1-23, 32-48, 50, 51, 53-58, 62-70, 73, 84-86, 95-99 are pending in the application.

2. In the prior action , the Final rejection of December 3, 2007, claims 1-23, 32-48, 50, 51, 53-58, 62-70, 73, 84-86, 95-99 were pending, with claims 8-13, 16-20, 33, 35, 36, 40-45, 51, 53-58, 62-70, 73, 86, and 95-99 withdrawn from consideration; claims 1-3, 7, 14, 15, 21-23, 37-39, 46-48, 50, 84, and 85 under consideration and rejected; and claims 4-6, 32, and 34 objected to.

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 3, 2008 has been entered.

In the submission, Applicant amended claim 21.

4. Claims 1-7, 14, 15, 21-23, 32, 34, 37-39, 46-48, 50, 84, and 85 are under consideration.

Claim Rejections - 35 USC § 112

5. **(Prior Rejection- Withdrawn)** Claims 21-23 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In view of the amendments to the claims, the prior basis of rejection is withdrawn.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. **(New Rejection- Necessitated by Amendment)** Claims 21-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

Claim 21 has been amended to require the providing step of claim 1 includes a step of dissociation of phage in "said sample." However, the providing step (step (b)) of claim 1 refers to "said bacteriophage exposed sample" whereas step (a) refers to "said sample" as the sample prior to the exposure of the sample to bacteriophage. The application as filed does not appear to provide support for a step of phage dissociation prior to the step of combining the sample with phage to create a bacteriophage exposed sample.

From Applicant's arguments, it appears that the claim is intended to read on the dissociation of the phage in "said bacteriophage exposed sample" rather than "said sample."

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. **(Prior Rejection- Maintained)** Claims 46-48 and 50 were rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi (WO 98/08944) in view of U.S. 5,789,174 (Mouton). The Applicant traverses the rejection by arguing that the claims do not require that use of negative control, and asserting that the reference may be positive if the bacteria are present in the sample. This argument is not found persuasive. Claim 46 specifically states that the reference indicates the assay result "if no target microorganism are present in said sample." Thus, the reference is a negative reference, i.e. a negative control; and the claim specifically excludes embodiments wherein the reference may be a positive control.

Applicant next asserts that the Examiner's reliance on a reference not referring to the use of bacteriophage is noted, but not found persuasive. Under the decision of *KSR International v. Teleflex*, the Supreme Court indicated that "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill." 82 U.S.P.Q.2d 185, at 1389 (U.S.S.C. 2007). While the statement was made with respect to devices, it would be equally obvious to use a technique to improve one method to improve similar methods. As was previously indicated, the Mouton reference indicates that it was known in the art to use negative control samples as means for improving bacterial detection systems. It would therefore have been apparent to those of ordinary skill in the art that such a control could be used to improve the method of Takahashi.

The fact that Mouton used different bacteria for use in the negative control is not found persuasive. First, the only requirement of the present claim is that the reference sample reflects

the absence of the target bacteria. Substituting a non-target bacteria for the target bacteria in the reference sample would meet this requirement.

For these reasons, and for the reasons of record, the rejection is maintained.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. **(Prior Rejection- Maintained)** Claims 1-3, 7, 14, 15, 37-39, 84, and 85 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4-6, 8-10 of copending Application No. 11/698,673. Moreover, in view of the teachings of claims 9 and 10 (referring to the use of immunoassays, which involve the use of antibodies to bind the target analyte) and of claim 3, the rejection is extended to claims 4, 6, and 32.

The Applicant traverses the rejection on three grounds.

First, the Applicant asserts that the present claims represent a qualitative measurement as to the presence of a target bacteriophage, while the copending claims represent a quantitative measurement. This argument is not found persuasive. In determining that the threshold concentration of target bacteria is present, as required by the copending claims, the method of that application would inherently determine if the target bacteria were present. I.e., the quantitative measurement of the copending application would inherently also provide the qualitative determination desired by the present claims. Thus, the copending claims represent a species of the presently claimed invention. Therefore there is no patentable distinction between the claim sets.

Second, the Applicant asserts that the waiting steps of the two claim sets differs in that the copending claims require the waiting be for a predetermined time. There is nothing in the present claims to exclude such a waiting time. Thus, again, the copending claims represent a species of the claimed invention.

Finally, the Applicant asserts that the copending claims require the use of predetermined amount of parent bacteriophage, and the measurement of a level of the bacteriophage. This argument is not found persuasive. First, there is nothing in the present claim to exclude an embodiment wherein a predetermined number of phage is used. Second, it is not clear how the fact that the copending claims require a determination as to the level of the bacteriophage (or a marker thereof) distinguishes the present claims (also requiring the determination as to the presence of such a marker or progeny phage). If the asserted difference again relates to the distinction between a qualitative and a quantitative determination, this argument is not found persuasive for the reasons indicated above.

The rejection is therefore maintained for the reasons above, and the reasons of record.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. **(New Rejection)** Claim 5 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4-6, 8-10 of copending Application No. 11/698,673 in view of Rittenburg et al. (US 5,710,005- of record in the action of July 2007). This claim is drawn to the method of claim 1, wherein the progeny phage is detection through the use of colored beads. The copending claims teachings the use of immunoassays and of chromatography. However, the claims do not specifically refer to the use of colored beads. However, as was previously described (pages 11-12 of action mailed July 2007), Rittenburg teaches that the use of immunoassays comprising the use of colored beads for the detection of analytes, such as viral antigens, was known in the art. Claims 13 and 14, and

column 3, line 67. It would therefore have been obvious to those of ordinary skill in the art to have used such methods in the detection of the markers of the copending claims. The present claims therefore represent an obvious embodiment of the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. **(New Rejection)** Claim 34 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4-6, 8-10 of copending Application No. 11/698,673 in view of Pearson et al. (U.S. 5,476,768). This claim is directed to embodiments of claim 1 wherein the phage is modified to over-express a detectable biomarker. While the copending claims suggest the modification of the phage to express a marker, the claims do not suggest the over-expression of such heterologous proteins. However, Pearson indicates that it was known in the art that phage could be modified to over-express reporter molecules and other heterologous proteins. Col. 10, lines 52-60. Because it would have been apparent that such an increase in the production of a detectable reporter would ease the detection of target bacteria (through detection of the increased amount of the marker) it would have been obvious to those of ordinary skill in the art to use phage modified not only to express a marker such as suggested by the copending claims, but to over-express such markers. The presently claimed invention therefore represents an obvious embodiment of the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/
Primary Examiner, Art Unit 1648